REMARKS/ARGUMENTS

The Status of the Claims:

The applicant requests an RCE under 37 CFR 1.114.

Claims 1-10 were pending in the present application before the amendment as set forth above. Among them, claims 8 and 9 were withdrawn from consideration as directed to non-elected subject matters. By this amendment, as set forth above, claim 1 is amended. In the August 22, 2007 Office Action, the Examiner rejected claims 1-5, 7, and 10 under 35 U.S.C. §103(a) as being unpatentable over PCT Pub. No. WO 89/09620, to Leskovar et al. (hereinafter "Leskovar"). Moreover, claims 1-7 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Leskovar as applied to claims 1-5, 7, and 10 above, and further in view of U.S. Pat. No. 6,200,754 to Housman et al. (hereinafter "Housman").

Applicant very appreciates the Examiner's careful review of the application.

In response, as set forth above, claim 1 has been amended to conform the claims to the embodiments of the present invention disclosed in the application, as originally filed.

Applicant asserts that no new matter is added.

The following remarks herein are considered to be responsive thereto.

35 U.S.C. §103(a) Rejections

In the August 22, 2007 Office Action, Claims 1-5, 7, and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Leskovar. Moreover, claims 1-7 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Leskovar as applied to claims 1-5, 7, and 10 above, and further in view of Housman.

Applicant respectfully traverses the rejection made by the Examiner at least for the reasons set forth below:

Claims 1-6:

As set forth above, among other unique limitations, amended claim 1 recites a pharmaceutical composition for cancer therapy essentially consisting of "***at least one compound***

having glutaminase activity; ***at least one antineoplastic agent*** selected from the group consisting of ***platinum complexes and anthracyclines***; and ***at least one of carrier substances, auxiliary substances, and pharmaceutical injection media***."

Support for the amendments can be found in the disclosure as originally filed, and specifically pages 5-7.

In the August 22, 2007 Office Action, the Examiner states "In summary Leskovar does teach a pharmaceutical composition containing 'at least one compound having glutaminase activity; and at least one antineoplastic agent selected from the group consisting of platinum complexes and anthracyclines.'... Leskovar et al. does not specifically teach the addition of both the anthracyclines and glutaminase enzymes in the same composition. However Leskovar et al. does teach that antibody conjugates of xenogeneic proteins can be admixed with Component A and either administered patenterally or orally. One of ordinary skill in the art would recognize that that a composition with active substances such as enzymes and anthracyclines would need to be mixed with a pharmaceutically acceptable carrier such as water to be administered patenterally or orally. It would therefore have been obvious for the person of ordinary skill in the art to modify the invention of Leskovar et al. to combine an enzyme such as glutaminase with component A, which they teach as an anthracycline such as doxorubicin. Leskovar et al. provides express motivation and reasonable expectation of success by stating that 'conjugates, composed of xenogeneous proteins...can be admixed to the component A'... Furthermore it would be obvious to combine the anthracycline and glutaminase since they are two components known for the same purpose... In this case the treatment of cancer."

However, these rejections are considered moot, in light of amended claim 1, which recites "a pharmaceutical composition for cancer therapy essentially consisting of ***at least one compound having glutaminase activity***; ***at least one antineoplastic agent*** selected from the group consisting of ***platinum complexes and anthracyclines***; and ***at least one of carrier substances, auxiliary substances, and pharmaceutical injection media***." Applicant respectfully submits that due to the amendment, any antibodies and conjugates thereof are excluded from the inventive composition. Moreover, Applicant submits that the problem underlying the present invention was to enhance the antiproliferative or antitumoral effect of known antineoplastic

agents or to reduce the dose of antineoplastic agents maintaining their pharmaceutical effect. This problem was solved by a combination of compounds having glutaminase activity and antineoplastic agents. The synergistic effect of the combination of the two components is explained by the energy depletion due to glutamine removal by glutaminase and the absence of glutamine for DNA synthesis that result in a prolongation of the cell division time und thus, in a prolongation of the phase in which the cancer cells are especially vulnerable to the cytostatic agents (see page 5). As can be impressively seen from the examples administration of a combination of the agents significantly reduces tumor growth of a variety of tumor types compared to administration of the individual compounds alone (see FIGS. 1-5). Thus, Leskovar et al. neither disclose the problem nor the solution of the present invention, and specifically, neither Leskovar nor Housman, taken alone or in combination, suggests or teaches a pharmaceutical composition for cancer therapy essentially consisting of "***at least one compound having glutaminase activity***; ***at least one antineoplastic agent*** selected from the group consisting of ***platinum complexes and anthracyclines***; and ***at least one of carrier substances, auxiliary substances, and pharmaceutical injection media***" according to amended claim 1 of the present invention. For at least the foregoing reasons, independent claim 1, as amended, is patentable under 35 U.S.C. § 103(a) over the cited references.

Accordingly, amended claims 2-6, which depend from now allowable amended claim 1, are patentable at least for this reason.

Claims 7 and 10:

Claim 7, as amended, among other unique limitations, discloses a process for producing the pharmaceutical composition as claimed in amended claim 1, and depends from amended claim 1. Referring to and incorporating herewith the above reasons why amended claim 1 is patentable, amended claim 7 is also patentable over the cited references at least because it depends from now allowable amended claim 1. Claim 10 depends from now allowable amended claim 7, and therefore should be also patentable at least for this reason.

Any amendments to the claims not specifically referred to herein as being included for the purpose of distinguishing the claims from cited references are included for the purpose of clarification, consistence and/or grammatical correction only.

CONCLUSION

Applicant respectfully submits that the foregoing Amendment and Response place this application in condition for allowance. If the Examiner believes that there are any issues that can be resolved by a telephone conference, or that there are any informalities that can be corrected by an Examiner's amendment, please call the undersigned at 404.495.3678.

Respectfully submitted,

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